REMARKS

Claims 1-4 and 18-29 have been cancelled without prejudice to their assertion in a continuing application. Claim 5 has been amended to recite the method of treatment of Alzheimer's disease. The subject matter removed from claim 5 was removed without prejudice to its assertion in a continuing application. Lastly, new claims 31 and 32 have been added. Support for new claims 31 and 32 can be found in original claims 3 and 4. No new matter has been introduced with these amendments.

With these amendments, claims 5-17 and 30-32 are pending.

1. Rejection under 35 U.S.C. § 112, 1st paragraph

Claims 1-17 and 30 were rejected under 35 U.S.C. § 112, 1st paragraph for allegedly lacking enablement. In particular, the Office asserts that the specification, "while being enabling for treatment of Alzheimer's disease, does not reasonably provide enablement for prophylaxis (i.e., prevention) of Alzheimer's disease." While applicants respectfully disagree with this rejection, in order to expedite the prosecution, the claims were amended to recite the treatment of Alzheimer's disease only. In light of this amendment, Applicants respectfully request reconsideration and withdrawal of the § 112, 1st paragraph rejection.

2. Rejection under 35 U.S.C. § 112, 1st paragraph

Claims 1-17 and 30 were rejected under 35 U.S.C. § 112, 1st paragraph for allegedly lacking enablement. In particular, the Office asserts that the specification, "while being enabling for treatment of Alzheimer's disease, does not reasonably provide enablement for the treatment of each and every species of dementia listed in the Markush group." While applicants respectfully disagree with this rejection, in order to expedite the prosecution, the claims were amended to recite the treatment of Alzheimer's disease only. Applicants respectfully request reconsideration and withdrawal of the § 112, 1st paragraph rejection.

3. Rejections under 35 U.S.C. § 112, 1st paragraph

Claims 1-17 and 30 were rejected for allegedly failing to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention, under the written description requirement of 35 U.S.C. § 112, first paragraph. In making this rejection, the Office asserts that the Applicants were not in possession of the invention at the time of filing because the specification lacks evidentiary support. Applicants respectfully disagree.

Under 35 U.S.C. § 112, first paragraph, all that is required to satisfy the written description requirement is that the specification describe the claimed invention in sufficient detail such that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991); MPEP § 2163(I). Possession is shown "by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163.02 (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir.1997)).

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. MPEP § 2163(I)(A) (citing *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976)). Thus, a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971); MPEP § 2163.04. Therefore, the Office must have a reasonable basis to challenge the adequacy of the written description and has the initial burden of presenting, by a preponderance of the evidence, why a person skilled in the art would not recognize in an Applicant's disclosure a description of the invention defined by the claims. See, e.g., *In re Wertheim*, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976); MPEP § 2163.04.

Contrary to the Office's assertion, Applicants' specification provides adequate written description such that one of skill in the art would recognize and conclude that the Applicants had possession of the invention as defined by the claims. For example, the specification discloses that the compounds of the invention are capable of inhibiting

beta-secretase (please see specification, page 32, lines 29-32). There is no evidence of record suggesting that the compounds of the invention do not inhibit beta-secretase.

Further, the specification also explicitly discloses biological assays that can be used to evaluate the compounds of the invention: enzyme inhibition assays for beta-secretase (Examples A, B, and C); an assay for beta-secretase inhibition with synthetic oligopeptide sequences (Example D); a cellular assay of beta-secretase activity (Example E); an animal model for Alzheimer's disease for inhibition of beta-secretase (Example F); and inhibition of A beta production in human patients (Example G). With respect to the state of the art, the assays described in the instant application are readily preformed by one skilled in the art. All the methods needed to practice the invention are well known in the art (*In re Wands* 858 F.2d at 740, 8 USPQ2d at 1406). As such, the experimentation required to screen the compounds of invention is routine to one skilled in the art, and not undue. MPEP 2164.06. Therefore, the instant specification provides more than ample guidance to one of ordinary skill in the art to use compounds of the invention as claimed.

Furthermore, the Office alleges that "the specification does not include any of the findings from any of the described assays to provide evidentiary support that [the compound of the invention] inhibits beta-secretase activity. Applicant's specification lacks drawings, data tables, or mere results..." Applicants respectfully submit that the MPEP does not require the submission of biological data to satisfy the written description requirement. If the Office disagrees, Applicants request that the specific section of the MPEP or the Code of Federal Regulations be made of record.

The specification satisfies the requirements set out in the MPEP for disclosure that satisfies a written description requirement. Consequently, Applicants respectfully request reconsideration and withdrawal of the § 112, 1st paragraph rejection.

4. Rejections under 35 U.S.C. § 103(a)

Claims 1-2 and 5-17 stand rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Bennett *et al.* (U.S. Pat. No. 5,693,815) and Esiri *et al.* (*J Neuro Neurosurg Psychiatry*, **1998**, *65*, 29-33). In particular, the Office asserts that Bennett discloses that the compounds of invention "are effective in the inhibition of HIV1

protease and have potential in the treatment of AIDS", and Esiri "teaches that AIDS patients have an increased prevalence of argyrophilic plaque deposition of beta amyloid". The Office then concludes that "it would have been *prima facie* obvious to one of ordinary skill in the art at the time of applicant's invention to use routine experimentation to determine if AIDS patients treated with compound A had reduced prevalence of argyrophilic plaques of beta amyloid." Applicants respectfully disagree.

Bennett does not teach methods for treatment of Alzheimer's disease nor any other neurodegenerative disease. That is, Bennett does not teach all claim limitations (i.e. method of treatment of Alzheimer's disease). In addition, there is no teaching or suggestion that the compounds of Bennett can be used in the treatment of Alzheimer's disease, nor is there is a reasonable expectation of success.

Esiri, on the other hand, discusses prevalence of beta amyloid plaques in AIDS patients. In particular, Esiri teaches that "there is a predisposition to argyrophilic plaque formation in the brain of AIDS" and that "the clinical relevance of [their] findings is, as yet, unclear" (see Abstract, conclusion at page 29, column 1, lines 30-36). Esiri also teaches that

> "[t]he extent of the Alzheimer's disease pathology that we found would not have been expected to give rise to symptoms of dementia on their own. However, some normally subclinical amounts of Alzheimer's disease pathology may contribute to clinical dementia if they are combined with other cerebral pathology such as vascular disease or Lewy body disease. So far the clinical studies of dementia in AIDS have suggested that, unlike Alzheimer's disease, the symptoms are indicative of a subcortical dementia." (emphasis added; see page 32, column 1, lines 28-39)

In other words, Esiri did not find prevalence Alzheimer's disease in AIDS patients. Rather, Esiri's findings "support the view that brain infection or cytokine production may influence the course of early stages of the putative pathogenic process postulated by the amyloid hypothesis of Alzheimer's disease" (see page 32, column 1, lines 42-46). Therefore, Esiri does not teach nor suggests the treatment of Alzheimer's disease.

More importantly, Esiri teaches away from the present invention. As noted by the Office, Esiri discloses that the anti-HIV treatments were ineffective a reducing the risk of plaque formation (see Office Action, page 15, lines 19-20; and Esiri page 31, column 2,

lines 23-27). Therefore, a person of ordinary skill in the art, having Esiri at hand, would not be motivated to "determine if AIDS patients treated with [compounds of the invention] had reduced prevalence of argyrophilic plaques of beta amyloid". That is, one of ordinary skill in the art reading Esiri would not expect the compounds of Bennett, which are used in the treatment of HIV, to be useful for the treatment of Alzheimer's disease.

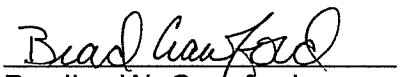
Therefore, applicants respectfully request that the Office withdraw the rejections of these claims based on 35 U.S.C. § 103(a).

CONCLUSION

Allowance of the claims and passage of the case to issue are respectfully solicited. The Applicants urge the Examiner to contact the Applicants' undersigned representative at (312) 913-2114, if she believes that a discussion would expedite prosecution of this application.

Respectfully submitted,

Dated: February 21, 2008

By: 

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